

TO: 9000-1 & 9333-1 ELISA Customer

FROM: Repligen Corporation

DATE: November 15, 2016

RE: Manufacturing Process Change for Protein A ELISA Kits; Part Numbers: 9000-1 and 9333-1.

This memo is to inform you of a process change related to the manufacture of Reagent C used in our ELISA kits, part numbers 9000-1 and 9333-1, used for the detection of leached Protein A. This change does not affect the use or operation of the final product.

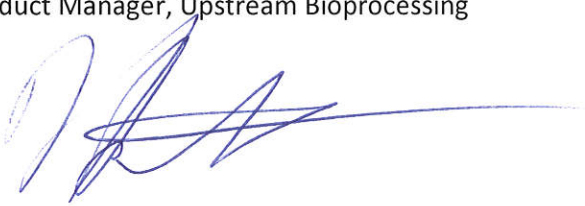
Recent information regarding immunization practices at our antibody raw material vendor has compelled us to implement a new purification step during the manufacture of Reagent C (Biotinylated Rabbit anti-Protein A). This new detection antibody purification step will ensure specificity to the desired target, leached Protein A.

The base raw material, anti-Protein A antibody derived from rabbits, used to manufacture Reagent C, will remain unchanged, as will the vendor of the base raw material. An affinity based purification step to eliminate potential cross-reactivity in the detection antibody has been implemented. This step will ensure the specificity of the reagent is preserved, and consistent, on a lot-to-lot basis.

We have proceeded to build product in accordance with this change. All Protein A ELISA kits manufactured from the date of this notification will include this Reagent C manufacturing change.

This change does not impact the final form, fit, functional performance, operating protocols or shelf life/expiration dating of the ELISA kits. If you have further questions or concerns, please do not hesitate to contact us for further information.

Harris Grevelis
Product Manager, Upstream Bioprocessing



Claire McGrath
Sr. Director, Quality

